# **Complete Summary**

#### **GUIDELINE TITLE**

Laparoscopic surgery for colorectal cancer (review).

## **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Laparoscopic surgery for colorectal cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Aug. 25 p. (Technology appraisal guidance; no. 105).

## **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

## SCOPE

# **DISEASE/CONDITION(S)**

Colorectal cancer

**DISCLAIMER** 

# **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Management Treatment

## **CLINICAL SPECIALTY**

Colon and Rectal Surgery Gastroenterology Oncology

### **INTENDED USERS**

Advanced Practice Nurses Physician Assistants Physicians

## **GUIDELINE OBJECTIVE(S)**

To determine the clinical effectiveness and cost-effectiveness of laparoscopic, laparoscopically assisted, and hand-assisted laparoscopic surgery (HALS) in comparison with open surgery for the treatment of colorectal cancer

# **TARGET POPULATION**

Adults with colorectal cancer

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Laparoscopic surgery for colorectal cancer (includes laparoscopically assisted and hand-assisted laparoscopic surgery [HALS])

## **MAJOR OUTCOMES CONSIDERED**

- Short-term clinical outcomes
  - Duration of operation
  - Anastomotic leakage
  - Abdominal wound breakdown
  - Lymph node retrieval
  - Number of ports used for laparoscopic resection
  - 'Opposite' method initiated
  - Completeness of resection, margins of tumour clearance
  - Conversion
  - Seroma
  - Blood loss
  - Wound infection
  - Urinary tract infection
  - Vascular injury
  - Visceral injury
  - 30-day mortality
  - Length of stay
  - Post operative pain
  - Time to return to usual activities
- Long-term clinical outcomes
  - Overall survival
  - Disease-free survival
  - Health-related quality of life
  - Recurrence

- Incisional hernia
- Port site hernia
- Cost-effectiveness

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Patient Registry Data
Searches of Unpublished Data

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by Aberdeen Health Technology Assessment Group (Health Services Research Unit, and Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen) (See the "Availability of Companion Documents" field.)

## **Clinical Effectiveness**

## **Search Strategy**

Electronic searches were undertaken to identify published and unpublished reports of randomized controlled trials (RCTs) and systematic reviews evaluating the effectiveness of laparoscopic and hand-assisted laparoscopic (HAL) surgery for colorectal cancer. Searches were restricted to the years 2000 onwards without language restriction and included abstracts from recent conference proceedings.

The main databases searched were: Medline (2000 to May Week1 2005), Excerpta Medica Database (EMBASE) (2000 to Week 19 2005), Biosciences Information Service (BIOSIS) (2000 to May 2005), Science Citation Index (2000 to 27th May 2005), Medline Extra (11th May 2005), Cochrane Controlled Trials Register (The Cochrane Library, Issue 2 2005), Cochrane Database of Systematic Reviews (The Cochrane Library, Issue 2,2005), Database of Abstracts of Reviews of Effectiveness (May 2005), HTA Database (May 2005), Health Management Information Consortium (2000 to May 2005) and Journals @ Ovid Full Text (2000 to July 2005 for selected surgical journals). In addition, recent conference proceedings and reference lists of all included studies were scanned to identify additional potentially relevant studies. Full details of the search strategies used are documented in Appendix 1 of the Assessment Report (see the "Availability of Companion Documents" field).

All titles and abstracts identified in these ways were assessed to identify potentially eligible studies. Two reviewers independently assessed them for

inclusion, using a study eligibility form developed for this purpose (see Appendix 2 of the Assessment Report [see the "Availability of Companion Documents" field). Any disagreements were resolved by consensus or arbitration. Systematic reviews were used to identify pre-2000 RCTs but were not included in this review. Lead authors of all included RCTs were contacted directly to identify further studies and unpublished data.

## **Inclusion and Exclusion Criteria**

## Types of Studies

The Assessment Group included individual RCTs and individual patient data meta-analyses of RCTs of laparoscopic surgery, laparoscopic-assisted surgery, and hand-assisted laparoscopic surgery (HALS) compared to open surgery for colorectal cancer. United Kingdom (UK) registries, providing data for a minimum of three years follow-up for any of the surgical techniques either alone or in comparison with each other, were also included. Studies were eligible irrespective of the language in which they were reported. Initially, the Assessment Group had intended to include cohort studies with a minimum follow-up of three years, but in the event they decided that this was not necessary as the length of follow-up available from RCTs (and particularly an individual patient data meta-analysis of RCTs) was considered sufficient to provide long-term data that were more robust than data from nonrandomized cohort studies.

## Types of Participants

Studies of adults with colorectal cancer who have undergone surgery were included. Patients undergoing palliative treatment (non-curative surgery) were excluded. In addition, the following subgroups were considered: location of cancer; stage of cancer; and mean age at diagnosis.

## Types of Outcomes

Short-term and long-term measures of outcomes were sought. See the "Major Outcomes Considered" field.

## **Data Extraction Strategy**

The titles and abstracts of all papers identified by the search strategy were screened. Full text copies of all potentially relevant studies were obtained and two reviewers independently assessed them for inclusion. Reviewers were not blinded to the names of studies' authors, institutions, or sources of the reports. Any disagreements were resolved by consensus or arbitration.

A data extraction form was developed to record details of trial methods, participants, interventions, patient characteristics and outcomes (see Appendix 3 of the assessment report [see the "Companion Documents" field). Two reviewers independently extracted data from the included studies. Any differences that could not be resolved through discussion were referred to an arbiter.

#### **Cost Effectiveness**

## **Search Strategies**

Studies that reported both costs and outcomes of laparoscopic and/or hand-assisted laparoscopic surgery techniques compared to open surgery for the treatment of colorectal cancer were sought from the systematic review of the literature. No language restrictions were imposed but as this review is an update of an earlier review conducted in 2000, the searching was limited to studies published between 2000 to 2005.

Databases searched were Medline (2000 to May Week 2 2005), Embase (2000 to Week 21 2005), Medline Extra (23rd May 2005), Science Citation Index (2000 to 27th May 2005), National Health Service Economic Evaluation Database (NHS EED), (May 2005), HTA Database (May 2005), Health Management Information Consortium (2000 to May 2005) and Journals @ Ovid Full Text (2000 to July 2005 for selected surgical journals). In addition, recent conference proceedings and reference lists of all included studies were scanned to identify additional potentially relevant studies. Other sources of information consulted included: references in relevant articles; selected experts in the field; references of consultees' submissions. Full details of the search strategies used are documented in Appendix 1 of the Assessment Report (see the "Companion Documents" field).

#### **Inclusion and Exclusion Criteria**

To be included, studies had to compare, in terms of both costs and outcomes, strategies involving laparoscopic and/or hand-assisted laparoscopic surgery compared to open surgery for treatment of colorectal cancer. Studies were included even if they made no formal attempt to relate cost to outcome data in a cost-effectiveness or cost-utility analysis. One reviewer assessed all abstracts for relevance and full papers were obtained for those that appeared potentially relevant.

#### **Data Extraction Strategy**

See section 4.1.3 of the Assessment Report (see "Availability of Companion Documents" field) for a list of the data extracted from each included primary study.

## **NUMBER OF SOURCE DOCUMENTS**

#### **Clinical Effectiveness**

In total, 46 reports on 20 studies (19 randomized controlled trials [RCTs] and one individual patient data meta-analysis) were included in the review of clinical effectiveness.

#### **Cost Effectiveness**

Of the studies selected for assessment, three studies met the inclusion criteria. Two additional unpublished papers were obtained from experts in the field.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Review of Published Meta-Analyses Systematic Review with Evidence Tables

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by Aberdeen Health Technology Assessment Group (Health Services Research Unit, and Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen) (See the "Availability of Companion Documents" field.)

#### **Clinical Effectiveness**

## **Quality Assessment Strategy**

Two reviewers, working independently, assessed the methodological quality of the included studies. Again, any disagreements were resolved by consensus or arbitration. The methodological quality of the meta-analysis was assessed by a previously validated 9-item checklist (see Appendix 4 of the Assessment Report [see the "Availability of Companion Documents" field). Primary randomized controlled trials (RCTs) were assessed using the Delphi criteria list (see Appendix 5 of the Assessment Report [see the "Availability of Companion Documents" field).

# **Data Synthesis**

For trials with multiple publications, only the most up to date data for each outcome were included. Dichotomous outcome data were combined using the Mantel-Haenszel relative risk (RR) method and continuous outcomes were combined using the inverse variance weighted mean difference (WMD) method. 95% confidence intervals (CI) and p values were calculated for the estimates of RR and WMD. The results are all reported using a fixed effects model. Chi-squared tests and I-squared statistics were used to explore statistical heterogeneity across studies and, when present, random effects methods were applied. Other possible reasons for heterogeneity were explored using sensitivity analyses. The meta-analyses were conducted using the standard Cochrane software RevMan 4.2.

Due to the lack of uniformity of the data presented by many studies, a qualitative review looking for consistency between studies was also performed. This was supplemented where appropriate by the investigation of the consistency in the direction of the results using the Sign test.

Opposite method initiated was defined as a laparoscopic operation initiated when an open resection was allocated, or vice-versa. Duration of operation was defined as time from first incision to last suture or, where this was not available, time in theatre or duration of anaesthesia. Length of hospital stay was defined as time from admission to discharge. A conversion was defined as a procedure initiated as laparoscopic but converted to an open procedure.

### **Cost Effectiveness**

## **Quality Assessment Strategy**

One economist assessed included studies using the National Health Service Economic Evaluation Database [NHS EED], guidelines for reviewers. The systematic review provided by the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI) was assessed using the following criteria used in a recent study of the quality of systematic reviews of economic evaluations.

The following questions were addressed for the quality assessment of reviews:

- A. Is it unlikely that important relevant studies were missed?
- B. Were the inclusion criteria used to select articles appropriate?
- C. Was the assessment of studies reproducible?
- D. Were the design and/or methods and/or topic of included studies broadly comparable?
- E. How reproducible are the overall results?
- F. Will the results help resource allocation in healthcare?

Each stem (A to F) was answered by one of the following: "Impossible to judge," "No," "Partly," "Yes."

## **Data Synthesis**

No attempt was made to synthesise quantitatively the primary studies that were identified. Data from all included studies were instead summarised and appraised in order to identify common results, variations and weaknesses between studies. If a study did not report incremental cost effectiveness ratios (ICERs) but provided sufficient data, then, where possible, the data were reanalysed to provide estimates of ICERs. The data were then interpreted alongside the results of the systematic review of effectiveness so that conclusions could be drawn on the relative efficiency of the different surgical strategies. The results of the systematic review of economic evaluations reported in this chapter were compared to those drawn from the consultee submissions and similarities and differences highlighted.

# METHODS USED TO FORMULATE THE RECOMMENDATIONS

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

## **Considerations**

Technology appraisal recommendations are based on a review of clinical and economic evidence.

## **Technology Appraisal Process**

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

# Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who

are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

- The Assessment Group conducted a systematic review of economic evaluations published from 2000 to 2005 and performed an independent economic evaluation. The consultees did not submit any formal economic evaluation of the technology. Instead, key issues were identified and highlighted in the submissions.
- The Assessment Group identified five relevant primary studies. Two were United Kingdom (UK) studies: an unpublished draft paper on the short-term economic evaluation of a subset of patients in the CLASICC trial, and a small study in the context of an enhanced recovery programme. When compared with open surgery, the mean cost for laparoscopic surgery was higher in all of the studies except one. There was considerable variation in the reported differences in mean costs of laparoscopic and open surgery in the studies.

See section 4.2 in the original guideline document for the full discussion of the cost effectiveness evidence and interpretation.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

## **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

- Laparoscopic (including laparoscopically assisted) resection is recommended as an alternative to open resection for individuals with colorectal cancer in whom both laparoscopic and open surgery are considered suitable.
- Laparoscopic colorectal surgery should be performed only by surgeons who
  have completed appropriate training in the technique and who perform this
  procedure often enough to maintain competence. The exact criteria to be
  used should be determined by the relevant national professional bodies.
  Cancer networks and constituent Trusts should ensure that any local
  laparoscopic colorectal surgical practice meets these criteria as part of their
  clinical governance arrangements.
- The decision about which of the procedures (open or laparoscopic) is undertaken should be made after informed discussion between the patient and the surgeon. In particular, they should consider:
  - The suitability of the lesion for laparoscopic resection
  - The risks and benefits of the two procedures
  - The experience of the surgeon in both procedures

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

- This guideline is intended to guide the clinician with decision-making regarding the appropriateness of laparoscopic, laparoscopically assisted, and hand-assisted laparoscopic surgery (HALS) in comparison with open surgery for the treatment of colorectal cancer.
- The data indicate that after laparoscopic resection, length of hospital stay is shorter, blood loss and post-operative pain are less, and return to usual activities is likely to be faster than after open resection.

## **POTENTIAL HARMS**

- Surgical complications (e.g., anastomotic leakage, abdominal wound breakdown, incisional hernia, wound and urinary tract infections)
- Operative mortality

## **CONTRAINDICATIONS**

## **CONTRAINDICATIONS**

Laparoscopic treatment is contraindicated in patients who have significant bowel dilatation or who are intolerant of a pneumoperitoneum. Furthermore, conversion from laparoscopic to open surgery may negate any advantage of an initial laparoscopic approach. Consequently, patients at high risk of conversion from laparoscopic to open surgery should be identified preoperatively and receive open surgery. Factors that may be relevant include body habitus, extensive peritoneal adhesions, and local spread of the tumour.

## **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health," issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (<u>www.nice.org.uk/TA105</u> [see also the "Availability of Companion Documents" field]).
  - Costing report and costing template to estimate the savings and costs associated with implementation
  - Audit criteria (see appendix C in the original guideline document).

# **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Living with Illness

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Laparoscopic surgery for colorectal cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Aug. 25 p. (Technology appraisal guidance; no. 105).

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2006 Aug

## **GUIDELINE DEVELOPER(S)**

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

# **SOURCE(S) OF FUNDING**

National Institute for Health and Clinical Excellence (NICE)

## **GUIDELINE COMMITTEE**

Appraisal Committee

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Laparoscopic surgery for colorectal cancer (review). Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Aug. 2 p. (Technology appraisal 105). Available in Portable Document Format (PDF) from the <u>National Institute for Health and Clinical Excellence</u> (NICE) Web site.
- Costing template and costing report. Laparoscopic surgery for colorectal cancer (review). London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Aug. Various p. (Technology appraisal 105). Available in Portable Document Format (PDF) from the NICE Web site.
- Systematic review of the clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer. Assessment report. Aberdeen Health Technology Assessment Group. 2005 Nov 15. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1097. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the <u>original guideline</u> <u>document</u>.

## **PATIENT RESOURCES**

The following is available:

Laparoscopic surgery for colorectal cancer (review). Understanding NICE guidance. Information for people who use NHS services. London (UK):
 National Institute for Health and Clinical Excellence (NICE); 2006 Aug. 4 p. (Technology appraisal 105).

Electronic copies: Available in Portable Document Format (PDF) from the <u>National Institute for Health and Clinical Excellence (NICE) Web site</u>. Also available in Welsh from the NICE Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1098. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## **NGC STATUS**

This NGC summary was completed by ECRI on February 22, 2007.

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Date Modified: 9/22/2008

